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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/607,121

06/26/2003

Meir Rosenberg

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NUTTER MCCLENNEN & FISH LLP  
WORLD TRADE CENTER WEST  
155 SEAPORT BOULEVARD  
BOSTON, MA 02210-2604

EXAMINER

DEAK, LESLIE R

ART UNIT

PAPER NUMBER

3761

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/05/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/607,121

Applicant(s)

ROSENBERG, MEIR

Examiner

Leslie R. Deak

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 19, 20 and 22 is/are rejected.
- 7) ☐ Claim(s) 10-18 and 21 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5 May 2006 has been entered.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-9 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,810,761 to Saens-Arrollo.

In the specification and figures, Saens-Arrollo discloses the device as claimed by applicant. With regard to claim 1, Saens-Arrollo discloses a pressure controlled cranial shunt comprising a body or housing made of domes 2 and 7 with an inlet (generally at 4), outlet (unlabeled, left side) and a pressure control device or valve mechanism with a bellows-shaped biocompatible elastomeric biasing element C. The valve further comprises a valve seat B and a blocking member in the form of annular ring I (see FIGS).

With regard to applicant's claim limitation that the valve has a self-adjusting resistance to fluid flow to provide a specific drainage activity, applicant sets forth no structural limitations that differentiate the instantly claimed valve from the Saens-Arollo device. Applicant discloses in paragraphs 0035-0037 of the specification that movement of fluid in and out of the bellows and the resulting pressure change within the bellows, adjusts the resistance of the bellows, resulting in a self-adjusting resistance to fluid flow. The Saens-Arollo device comprises the same structural features. Pressure from the valve inlet at 4 unseats the valve blocking plate H from valve seat B, and allows fluid to flow through the bellows, adjusting the pressure within the bellows, to the outlet L. As such, the operation of the bellows is self-regulating as claimed and disclosed by applicant.

With regard to claim 2, the biasing member or bellows is connected to the valve as a whole by threaded cap B which has perforations D and L, allowing fluid flow through the valve into the chamber (see FIGS).

With regard to claims 3, Saens-Arollo's bellows member is resilient, meeting applicant's limitation drawn to a spring.

With regard to claims 4-7, Saens-Arollo discloses a bellows F with a base plate H, end plate G that connects to support member 5 with aperture L, and a collapsible sidewall (see FIGS 1-3).

With regard to claims 8 and 9, Saens-Arollo discloses that the bellows is made from a biocompatible elastic material, and comprises openings K to provide

communication between the bellows and the valve chamber (see column 1, lines 55-60, FIG 3).

With regard to claim 22, applicant claims that the biasing member has a “damped resistance” but provides no structural limitations that contribute to such a resistance. Since there are no structural limitations that distinguish the claimed apparatus from the Saens-Arollo valve, the prior art meets the limitations of the claims.

4. Claims 1, 3-7, 9, 19, 20, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by US 3,450,155 to Froehner et al.

Froehner discloses a pressure relief valve with a housing 12 with a chamber, an inlet port 14, outlet port 25, a valve mechanism with a valve seat with a groove 28 that mates with blocking member, ball 23, and a biasing member or bellows assembly 15 that exerts force against ball 23. The biasing element or bellows compresses with increased pressure, unseating the blocking member 23 and allowing fluid to flow through the housing (see FIG 1, column 1, line 55 to column 2, line 23).

With regard to applicant’s claim limitation that the valve has a self-adjusting resistance to fluid flow to provide a specific drainage activity, applicant sets forth no structural limitations that differentiate the instantly claimed valve from the Froehner device. Applicant discloses in paragraphs 0035-0037 of the specification that movement of fluid in and out of the bellows and the resulting pressure change within the bellows, adjusts the resistance of the bellows, resulting in a self-adjusting resistance to fluid flow. The Froehner device comprises the same structural features. Pressure from the valve inlet at 14 unseats the valve blocking ball 23 from valve seat with groove 28, and allows

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fluid to flow through the bellows, adjusting the pressure within the bellows, to the outlet

25. As such, the operation of the bellows is self-regulating as claimed and disclosed by applicant.

With regard to claim 3, Froehner specifically discloses that the biasing element may comprise a spring 29 (see FIG 3, column 2, lines 34-40).

With regard to claims 4 and 5, the single bellows 15 comprises a base plate 19, end plate 17, and flexible wall 16 therebetween (see FIG 1).

With regard to claim 6, the end plate connects to a support member 18/24 for securing the end plate within the housing (see FIG 1).

With regard to claim 7, the support member 24 includes apertures 25 for permitting fluid flow (see FIG 1).

With regard to claim 9, the end plate 17 comprises a large central aperture (unlabeled) that permits fluid flow between the bellows and the outlet of the valve chamber.

With regard to claim 22, applicant claims that the biasing member has a "damped resistance" but provides no structural limitations that contribute to such a resistance.

Since there are no structural limitations that distinguish the claimed apparatus from the Froehner valve, the prior art meets the limitations of the claims.

***Allowable Subject Matter***

5. Claims 10-18 and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. The following is a statement of reasons for the indication of allowable subject matter: The prior art fails to disclose or suggest the device claimed by applicant.

With regard to claims 10-18, the prior art fails to disclose the valve of claim 1 in combination with a second bellows, wherein the first and second bellows are sequentially connected. As pointed out by applicant, the second claimed bellows is not a mere duplication of the working parts of the devices found in the prior art, since the two bellows work in a coordinated relationship to provide a pressure dampening effect not suggested in the prior art.

With regard to claim 21, the prior art fails to disclose the valve of claim 1 in combination with a configuration that permits passage of fluid from inlet to chamber without passing through the biasing element. The best prior art of record, Saens-Arollo and Froehner both require fluid to pass through the biasing element during the valving operation. As such, the claimed configuration is not suggested in the prior art.

#### ***Response to Arguments***

7. Applicant's amendment and arguments filed 5 May 2006 have been entered and considered.

8. Applicant's arguments with respect to the 35 USC 103 rejection of claims under Saens-Arollo and Southworth have been fully considered and are persuasive. The 35 USC rejection of claims 10-21 has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Froehner with regard to claims 19 and 20.

Applicant's arguments with regard to the 35 UCS 102 rejection of claims 1-9 have been fully considered but they are not persuasive. Applicant argues that the prior art does not have a self-adjusting resistance to fluid flow to provide a specific drainage activity. However, applicant sets forth no structural limitations that differentiate the instantly claimed valve from the prior art devices. The prior art devices, as set forth above, operate in the same manner as disclosed by applicant, wherein fluid flow in and out of the bellows adjusts the resistance of the bellows, creating a self-adjusting resistance. Therefore, the devices found in the prior art have just as much self-adjusting capability as the device claimed by applicant.

Applicant further argues that the prior art does not allow fluid to release at a rate which is proportional to an average pressure difference over time. Applicant sets forth that this limitation is functional, and must be considered as such. Again, applicant fails to set forth any structural limitations that provide such a function. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). "[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). (See MPEP 2114.) Therefore, in the absence of any structural difference between the instant invention and the prior art, the instantly claimed valve is unpatentable over the prior art of record.

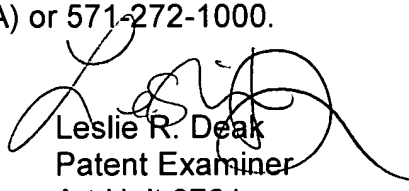


**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leslie R. Deak  
Patent Examiner  
Art Unit 3761  
21 December 2006